AUG 13 2013

510(K) SUMMARY FOR ALTIMATE MEDICAL'S EASYSTAND BANTAM MEDIUM

This summary of 510(K) safety and effectiveness information is being supplied in accordance with the requirements of the SMDA of 1990 and 21 CRF 807.92

The assigned 510(k) number is K123834.

Date: December 12, 2012

Submitted by: Invacare Corporation
Registration No. 1525712
One Invacare Way
Elyria, Ohio 44035-4190

Manufacturer: Altimate Medical
Registration No. 2183634
262 W. First Street
Morton, MN 56270

Telephone: 440-329-6356
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Contact Person: Mr. Bob Rogers

Trade Name: EasyStand Bantam Medium

Common Name: Electric Lift Chair

Classification Name: Chair, positioning, electric per 21 CFR 890.3110

Legally Marketed Predicate Device(s): Altimate Medical EasyStand Bantam: K091242
July 6, 2009

Yes, you can.

Device Description: The EasyStand Bantam Medium is a standing frame for indoor use that allows users with various degrees of physical disability to be supported in a standing, weight-bearing position. The device is a sit-to-stand stander with the option of supine positioning. The optional Shadow Tray supports the user from sitting to standing and can be used as a desk/workstation in the seated and /or standing position. The device offers two options to raise the seat, the standard manual hydraulic lift or the optional Pow'r Up lift. The Bantam Medium accommodates most individuals within the height range of 48"-66" and up to 200 lbs.

Intended Use: To assist persons who have difficulty rising from a seated position to a standing position and is indicated for persons weighing up to 200 lbs.

Substantial Equivalence: Products that are substantially equivalent to the Altimate Medical EasyStand Bantam Medium is the Altimate Medical EasyStand Bantam K091242, July 6, 2009.

The EasyStand Bantam Medium is comparable to the EasyStand Bantam in its intended use, construction and functionality. The intended use of providing support for persons in a standing position, providing a means for a person to rise from a seated to a fully standing position and offering a method of exercising the body remains the same between the two devices. Two of the lifting features are the same in both devices in that elevation is accomplished either manually by a user operated hydraulic oil cylinder or electrically by a battery powered linear actuator motor that is activated by a hand pendant.
The main difference between the two devices is as follows:

- The user population. The EasyStand Bantam Medium accommodates most individuals ranging in height from 48"- 66" (122cm-168cm) and up to 200 lbs. (91kg). The Bantam EasyStand Extra Small and Small is intended for smaller individuals, including pediatrics (the extra small accommodates most individuals ranging in height from 28"- 40" (71cm-102cm) and up to 50 lbs. (23kg) and the small accommodates most individuals ranging in height from 36"-54" (91cm-137cm) and up to 100 lbs. (45kg).
- The EasyStand Bantam Medium has a single control handle that operates the functions associated with the supine option.
- The EasyStand Bantam Medium back angle adjustment is independent of the following arm and the tray.

Performance Standards: Although no performance standards or special controls have been developed for electric positioning chairs under Section 514 of the FD & C Act, Altimate Medical has chosen to test the EasyStand Bantam Medium against the following standards and the reports are enclosed herein:

- IEC 60601-1 (3rd Edition) and CSA C22.2#60601-1 (3rd Edition) for basic safety and performance, including risk management;

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- IEC 60601-1 (2nd Edition) to address medical electrical equipment general requirements for safety. The EasyStand Bantam Medium and predicate devices all meet IEC 60601-1 (2nd Edition), including mechanical strength testing for the claimed weight capacities.

- IEC 60601-1-11 to address specific requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment;

- IEC 60601-1-2 to address Class B emissions and immunity for non-life-supporting equipment; and,

- BS EN 12182:1999 to address safety requirements for medical electrical systems. Included in this test report, load testing results support EasyStand Bantam Medium substantial equivalency.

The results of these tests demonstrate and support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 13, 2013

Altimate Medical, Inc.
% Ms. Stacey Frank
Director of Operations
262 West First Street
Morton, MN 56270

Re: K123834
Trade/Device Name: EasyStand Bantam Medium
Regulation Number: 21 CFR 890.3110
Regulation Name: Electric Lift Chair
Regulatory Class: Class II
Product Code: INO
Dated: July 2, 2013
Received: July 9, 2013

Dear Ms. Frank:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123834

Device Name: EasyStand Bantam Medium

Indications for Use: The Altimate Medical EasyStand Bantam Medium is intended to assist persons who have difficulty rising from a seated position to a standing position and is indicated for persons weighing up to 200lbs.

Prescription Use ✓ **AND/OR** **Over-The-Counter Use** ____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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